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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,898	01/16/2004	Fateme Sima Sariaslani	CL2035USNA	1246

23906 7590 10/19/2006

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WILMINGTON, DE 19805

EXAMINER

FRONDA, CHRISTIAN L

ART UNIT PAPER NUMBER

1652

DATE MAILED: 10/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/759,898	<b>Applicant(s)</b> SARIASLANI ET AL.	
	<b>Examiner</b> Christian L. Fronda	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11, 12 and 14 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-9, 11 and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                           | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

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### DETAILED ACTION

1. Claims 1-9, 11, 12, and 14 are pending in the instant application. Claims 1 and 14 have been previously withdrawn from consideration as drawn to a non-elected invention.
2. Claims 2-9, 11, and 12 are under consideration in this Office Action.
3. The objection to the title has been withdrawn in view of applicants' amendment to the title dated 07/28/2006.
4. The objection to claims 3-9, 11, and 12 has been withdrawn in view of applicants' amendment to the claims filed 07/28/2006, where the amended claims now depend from claim 2.
5. The rejection of claims 2-9, 11, and 12 under 35 U.S.C. 112, second paragraph, has been withdrawn in view of applicants' arguments and amendments to the claims filed 07/28/2006.

### *Claim Rejections - 35 U.S.C. § 112, 1st Paragraph*

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
7. Claims 2-9, 11, and 12 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants' arguments filed 07/28/2006 have been fully considered but are not persuasive for reasons of record as further explained below.  
The amended claims are drawn to a method comprising the use of a genus of *E. coli* yhcP genes and variants thereof, and a genus of *E. coli* yhcQ genes and variants thereof. The scope of each genus includes many members which have widely differing structural, chemical, and physiochemical properties including widely differing nucleotide sequences. Furthermore, each

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genus is highly variable because a significant number of structural differences between genus members exists.

While the specification discloses the yhcP gene from *E.coli* as consisting of SEQ ID NO: 1 and the yhcQ gene from *E.coli* as consisting of SEQ ID NO: 2, the specification does not define any structural features, nucleotide sequences, and chemical characteristics commonly possessed by each genus. Thus, one skilled in the art cannot visualize or recognize the identity of the members of each genus for use in the claimed method. In contrast to the court of *Capon*, the instant invention is not drawn to chimeric polynucleotides encoding antibodies but instead is drawn to methods for making host cells that have increased resistant to aromatic carboxylic acids by transforming the host cells with different polynucleotides. Thus, the findings of the court of *Capon* do not apply to the instant invention.

In view of the above considerations, one of skill in the art would not recognize that applicants were in possession of each claimed genus of *E. coli* yhcP genes and variants thereof, and a genus of *E. coli* yhcQ genes and variants thereof for use in the claimed method.

As stated in the previous Office Action, gene elements which are not particularly described, including promoters, regulatory elements, and untranslated regions, are essential to the function of the claimed invention since the claims recite yhcP and yhcQ genes. The art indicates that the structure of genes with promoters, regulatory elements, and untranslated regions is empirically determined. Therefore, the structure of these elements which applicants considers as being essential to the function of the claim are not conventional in the art.

There is no known or disclosed correlation between the coding region of a polynucleotide encoding the efflux protein YhcP or YhcQ and the structure of the non-described promoter, regulatory elements, and untranslated regions of the yhcP gene or yhcQ gene, respectively.

In view of the above considerations, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of any yhcP gene and any yhcQ gene.

Amending the claims to recite that the claimed method comprises transforming *E.coli* host cells with the polynucleotide consisting of SEQ ID NO: 1 and the polynucleotide consisting of SEQ ID NO: 2 thereby increasing resistance of the *E.coli* host cell to the aromatic carboxylic acids para-hydroxybenzoic acid and para-hydroxycinnamic acid may overcome the rejection.

8. Claim 2-9, 11, and 12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for increasing the resistance of a host cell to aromatic carboxylic acids comprising transforming and overexpressing in a host cell the polynucleotide of SEQ ID NO: 1 and the polynucleotide of SEQ ID NO: 2; does not reasonably provide enablement for such method comprising transforming and overexpressing in a host cell

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any yhcP gene and any yhcQ gene of any nucleotide sequence and from any biological source. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicants' arguments filed 07/28/2006 have been fully considered but are not persuasive for reasons of record as supplemented below.

The nature and breadth of the amended claims encompasses any method for increasing the resistance of a host cell to aromatic carboxylic acids comprising transforming and overexpressing in a host cell any *E. coli* yhcP gene and variants thereof, and any *E. coli* yhcQ gene and variants thereof, where each of said any *E. coli* yhcP gene and any *E. coli* yhcQ gene is of any nucleotide sequence and structure.

Although the specification provides guidance for the yhcP gene from *E. coli* as consisting of the nucleotide sequence of SEQ ID NO: 1 and the yhcQ gene from *E. coli* as consisting of the nucleotide sequence of SEQ ID NO: 2, and a method for overexpressing said polynucleotides in an *E. coli* host cell thereby increasing resistance of the *E. coli* host cell to the aromatic carboxylic acids para-hydroxybenzoic acid and para-hydroxycinnamic acid, the specification does not provide guidance, prediction, and working examples for the claimed method using any *E. coli* yhcP gene and variants thereof, and any *E. coli* yhcQ gene and variants thereof, where each of said any *E. coli* yhcP gene and any *E. coli* yhcQ gene is of any nucleotide sequence and structure. Thus, an undue amount of trial and error experimentation must be preformed. Such experimentation involves determining whether over expressing *E. coli* yhcP gene and variants thereof, and any *E. coli* yhcQ gene and variants thereof in any host cell will result in the host cell having increased resistance to any aromatic carboxylic acid. General teaching regarding screening and searching for the claimed invention using assays taught in the specification is not guidance for making the claimed invention.

In view of the above considerations, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with the claims.

Amending the claims to recite that the claimed method comprises transforming *E. coli* host cells with the polynucleotide consisting of SEQ ID NO: 1 and the polynucleotide consisting of SEQ ID NO: 2 thereby increasing resistance of the *E. coli* host cell to the aromatic carboxylic acids para-hydroxybenzoic acid and para-hydroxycinnamic acid may overcome the rejection.

### ***Conclusion***

9. No claim is allowed.

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10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF

  
**TEKCHAND SAIDHA**  
**PRIMARY EXAMINER**